§ 172.130

Food	Limita- tion (parts per mil- lion)	Use
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.

- (c) To assure safe use of the additive:
- (1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.
- (2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.
- (d) In the standardized foods listed in paragraph (b) of this section, the additives are used only in compliance with the applicable standards of identity for such foods.

[42 FR 14491, Mar. 15, 1977, as amended at 48 FR 10815, Mar. 15, 1983; 58 FR 52222, Oct. 7, 1993; 60 FR 33710, June 29, 1995; 65 FR 48379, Aug. 8, 2000]

§172.130 Dehydroacetic acid.

The food additive dehydroacetic acid and/or its sodium salt may be safely used in accordance with the following prescribed conditions:

(a) The food additive meets the following specifications:

Dehydroacetic acid: Melting point, 109 $^{\circ}$ C-111 $^{\circ}$ C; assay, minimum 98 percent (dry basis). Sodium salt of dehydroacetic acid: Assay, minimum 98 percent (dry basis).

- (b) It is used or intended for use as a preservative for cut or peeled squash, and is so used that no more than 65 parts per million expressed as dehydroacetic acid remains in or on the prepared squash.
- (c) The label or labeling of any package of the additive intended for use in food shall bear adequate directions for use to insure compliance with this section.

§172.133 Dimethyl dicarbonate.

Dimethyl dicarbonate (CAS Reg. No. 4525–33–1) may be safely used in food in

accordance with the following prescribed conditions:

- (a) The additive meets the following specifications:
- (1) The additive has a purity of not less than 99.8 percent as determined by the following titration method:

PRINCIPLES OF METHOD

Dimethyl dicarbonate (DMDC) is mixed with excess diisobutylamine with which it reacts quantitatively. The excess amine is backtitrated with acid.

APPARATUS

250-milliliter (mL) Beaker 100-mL Graduate cylinder 25-mL Pipette

10-mL Burette (automatic, eg., Metrohm burette)
Stirrer

Device for potentiometric titration Reference electrode Glass electrode

REAGENTS

Acetone, analytical-grade
Solution of 1 N diisobutylamine in chlorobenzene, distilled
1 N Acetic Acid

PROCEDURE

Accurately weigh in about 2 grams of the sample (W) and dissolve in 100 mL acetone. Add accurately 25 mL of the 1 N dissolutylamine solution by pipette and allow to stand for 5 minutes. Subsequently, titrate the reaction mixture potentiometrically with 1 N hydrochloric acid (consumption=a mL) while stirring. For determining the blank consumption, carry out the analysis without a sample (consumption=b mL).

CALCULATION

$$\frac{(b-a)\times 13.4}{W} = \% DMDC$$

NOTE: For adding the diisobutylamine solution, always use the same pipette and wait for a further three drops to fall when the flow has stopped.

(2) The additive contains not more than 2,000 ppm (0.2 percent) dimethyl carbonate as determined by a method entitled "Gas Chromatography Method for Dimethyl Carbonate Impurity in Dimethyl Dicarbonate," whichis incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 5100 Paint Branch Pkwy., College Park, MD

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20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

- (b) The additive is used or intended for use as a microbial control agent in the following beverages under normal circumstances of bottling, canning, or other forms of final packaging, where the viable microbial load has been reduced to 500 microorganisms per milliliter or less by current good manufacturing practices such as heat treatment, filtration, or other technologies prior to the use of dimethyl dicarbonate:
- (1) In wine, dealcoholized wine, and low alcohol wine in an amount not to exceed 200 parts per million.
- (2) In ready-to-drink teas in an amount not to exceed 250 parts per million.
- (3) In carbonated or noncarbonated, nonjuice-containing (less than or equal to 1 percent juice), flavored or unflavored beverages containing added electrolytes (5-20 milliequivalents/liter sodium ion (Na+) and 3-7 milliequivalents/liter potassium ion (K+)) in an amount not to exceed 250 parts per million.
- (4) In carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent, in an amount not to exceed 250 parts per million.
- (c) To ensure the safe use of the food additive, the label of the package containing the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:
- (1) The name of the additive "dimethyl dicarbonate."
 - (2) The intended use of the additive.
- (3) Adequate directions for use to ensure compliance with this section.

[53 FR 41329, Oct. 21, 1988, as amended at 58 FR 6091, Jan. 26, 1993; 59 FR 5319, Feb. 4, 1994; 61 FR 14245, Apr. 1, 1996; 61 FR 26788, May 29, 1996; 66 FR 13653, Mar. 7, 2001]

§172.135 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the following prescribed conditions:

- (a) The additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate $(C_{10}H_{14}O_8N_2Na_2\cdot 2H_2O)$.
- (b) It is used or intended for use as follows:
- (1) Alone, in the following foods at not to exceed the levels prescribed, calculated as anhydrous calcium disodium EDTA:

Limita- tion (parts per mil- lion)	Use
150	With iron salts as a stabilizer for vitamin B 12 in liquid multivitamin preparations.
145	Promote color re- tention.
165	Preservative.
500	Promote color re- tention.
36	As a cure accel- erator with so- dium ascorbate or ascorbic acid.
75	Preservative.
75	Do.
100	Promote color re- tention.
150	Inhibit discoloration.
165	Promote color re- tention.
75	Preservative.
² 315	Promote color retention.
75	Preservative.
100	Do.
75	Do.
	150 145 165 500 36 75 75 100 165 75 100 75 1

¹ Based on total weight of finished product including packing medium. ² In dried banana component of cereal product.

(2) With calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate; calcium disodium (ethylenedinitrilo) tetraacetate), in the following foods at not to exceed, in combination, the levels prescribed, calculated as anhydrous $C_{10}H_{12}O_8N_2CaNa_2$:

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Food	Limita- tion (parts per mil- lion)	Use
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.